

REMARKS

The Office Action rejected claims 1-3, 5-9 and 11. Claim 4 was previously canceled, and claim 10 is currently withdrawn. By this Amendment, to expedite prosecution of this application, claims 1 and 9 are amended. Claims 1-3, 5-9 and 11 are currently pending in this application.

Interview Summary

The applicant thanks Examiner Lang for her participation in a telephone interview with Catherine D. Spolar and Brian Oberst. The participants discussed the rejections of claims 1 and 9 as previously presented based on U.S. Published Application No. 2003/0181935 (Gardeski). At the time of the interview, no agreement was reached.

Objection to the Specification

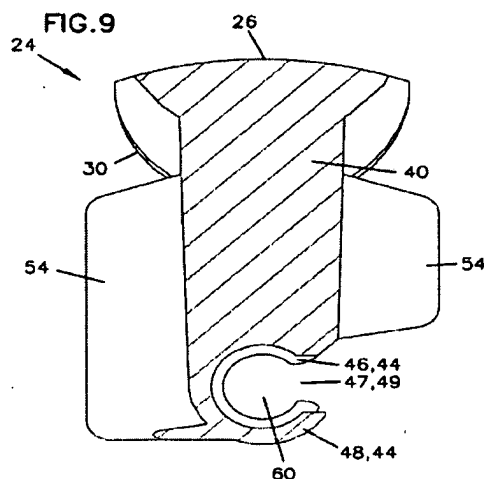
The Examiner objected to the specification as failing to provide antecedent basis for the claimed subject. The specification has been amended include to the description that "the side openings 47, 49 are configured to deform away from the lower edge of the lead body so as to enlarge the side opening." This description is supported by at least FIG. 9. No new matter has been entered.

Claim Rejections Under 35 U.S.C. § 103(a)

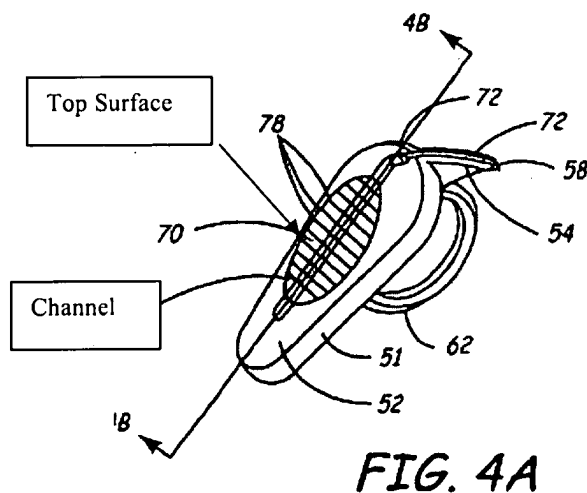
Claims 1-3, 5-9 and 11 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Gardeski et al. (US Patent Publication No. 2003/0181935 A1).

Without in any way acquiescing to the Office Action's characterization of the teachings of the *Gardeski* reference or of the pending claims, the Applicants have amended independent claims 1 and 9 to expedite prosecution of this application. Claims 1 and 9 each recite a device including a web and "a deformable side opening member extending in an arcuate manner from the lower portion of the web to a free edge so as to define a central opening having an inner diameter sized to engage the linear object, the web lower edge and the free edge spaced apart from one another such that they define a longitudinal side opening." See for example, FIG. 9 reproduced on the following page. Additionally, claims 1 and 9 each require the side opening member to be "configured to deform away from the lower edge of the body such that the free

edge is moveable relative to the web lower edge to allow the lead to be snapped into the central opening.”



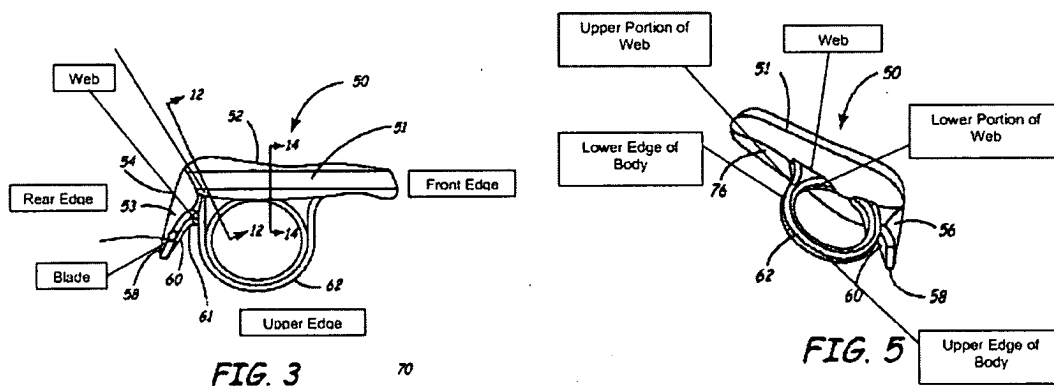
Gardeski, on the other hand, fails to disclose or fairly suggest at least a “side opening member” as claimed. *Gardeski* is directed to a slitting tool including a top surface 52 having a channel 72 that extends along at least a portion of the top surface 52 and further continues along at least a portion of front surface 54 of the nose 53 (paragraph [0047]). See for example FIG. 4A, reproduced below.



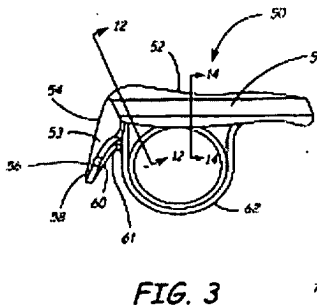
The Office Action asserts that:

Gardeski discloses a distal lead management segment (51) having an outer surface and comprising a side opening member, the rear or front opening ([0050]). The lumen through the side opening (72) overlaps the instantly claimed central opening since it is sized to engage the linear lead.

Office Action at 3. The Office Action thus associates both the claimed side opening and central opening with *Gardeski's* channel 72. The Office Action does not, however, clearly identify what feature(s) of *Gardeski* allegedly correspond to the claimed side opening member. Moreover, the Office Action's interpretation of *Gardeski's* alleged "web" appears to change from one figure to the next. Compare, for example, the reproduction of *Gardeski's* FIG. 3 provided on page 5 of the Office Action (below left), with the reproduction of *Gardeski's* FIG. 5 on page 6 of the Office Action (below right).



In any event, FIGS. 12-15 of *Gardeski* illustrate cross-sectional views of various embodiments of the Gardeski device taken at different locations as shown in FIG. 3. (FIGS. 3 and 12-15 reproduced below).



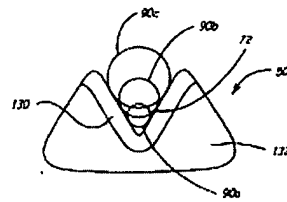


FIG. 12

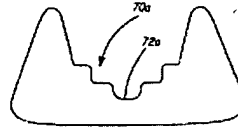


FIG. 13

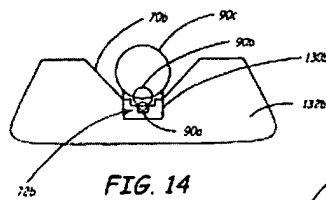


FIG. 14

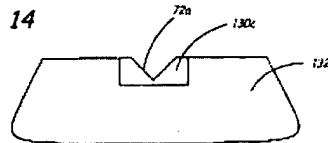


FIG. 15

As is clear from these figures, under the Office Action's interpretation of *Gardeski's* alleged "web," "side opening," and "central opening," *Gardeski* clearly cannot be interpreted to include the requirement of both claim 1 and claim 9 of "a deformable side opening member extending in an arcuate manner from the lower portion of the web to a free edge so as to define a central opening, ... the web lower edge and the free edge spaced apart from one another such that they define a longitudinal side opening."

Moreover, there is no apparent reason to modify the *Gardeski* device such that it includes a deformable side opening member as recited by claims 1 and 9, even if such a modification were possible given the numerous structural differences between the *Gardeski* device and the claimed device. *Gardeski* discloses that the channel 72 is provided to align a lead, delivery sheath, or body of another implantable device in relation to the delivery sheath and slit, "*but does not clamp or affix to the lead.*" (*Gardeski*, paragraph [0047]) (emphasis added). In contrast to the claimed invention, *Gardeski* teaches that the lead is "instead held in place by the user's thumb." (*Gardeski*, paragraph [0047]). In an alternative embodiment, *Gardeski* discloses that in one region, the channel 72 may be deep enough to receive the entire body of the lead 90.

However, a finger is still required to retain the lead within the channel. (*See Gardeski*, paragraph [0051]). *Gardeski* states that a thumb “ensures a fixed relationship between the slitting tool and the lead body.” Furthermore, *Gardeski*, in the background, alleges a number of disadvantages associated with devices configured to couple to a lead body or delivery sheath. (*See, e.g., Gardeski*, paragraph [0007] – [0009]). *Gardeski* thus teaches away from a resiliently deformable opening that allows a lead to be snapped into the opening as *Gardeski*.

Claims 1 and 9 are thus patentable over *Gardeski*. Dependent claims 2-3, 5-8 and 11 are also patentable for at those same reasons as discussed above. Withdrawal of the rejection is respectfully requested.

Conclusion

For the reasons explained above, all pending claims are now in condition for allowance. Accordingly, the applicant respectfully requests that the Office issue a Notice of Allowance.

Any amendments to the claims are made to expedite prosecution of this application, without acquiescing to the Office’s rejections or characterizations of the claims or references. Any claim amendments not specifically discussed or explained in the above remarks are not made for patentability purposes, and these claims would satisfy the statutory requirements for patentability without these amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, or to reduce the time and effort required of those skilled in the art to clearly understand the scope of the claim language. Even if not expressly discussed above, the applicant respectfully traverses each of the rejections, assertions, and characterizations regarding the disclosure and teachings of the cited references, including the prior art status and the propriety of proposed combinations of cited references.

The Applicants have made a good faith effort to respond to all rejections set forth in the Office Action and to place the pending claims in condition for immediate allowance. Nevertheless, if the Examiner identifies any remaining issues, she is invited to call the undersigned at 612-766-8245 to discuss.

Respectfully submitted,

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Dated: March 13, 2009